IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

BOEHRINGER INGELHEIM INTERNATIONAL GmbH and BOEHRINGER INGELHEIM PHARMACEUTICAL, INC., Plaintiffs, Counterclaim Defendants, v. MYLAN PHARMACEUTICALS INC., Defendant and Counterclaim Plaintiff.	Civil Action No.: 05-0854 (KAJ)

BRIEF IN SUPPORT OF MYLAN PHARMACEUTICALS INC.'S MOTION TO STRIKE PLAINTIFFS' ALLEGATIONS CONCERNING WILLFUL INFRINGEMENT AND TO BAR ALL DISCOVERY RELATED THERETO

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PRELIMINARY STATEMENT

Defendant Mylan Pharmaceuticals Inc ("Mylan") respectfully submits this brief in support of its motion pursuant to Fed. R. Civ. P. 12(f) to strike the allegations concerning willful infringement raised by Boehringer Ingelheim International GmbH and Boehringer Ingelheim Pharmaceutical Inc. (hereinafter referred to as "Plaintiffs") in the Complaint (D.I. 1), and to bar all discovery related to those allegations.

NATURE AND STAGE OF PROCEEDINGS

The Statutory Scheme Under The Hatch-Waxman Amendments

This is a patent infringement action brought by Plaintiffs pursuant to the Hatch-Waxman amendments to the Federal Food, Drug, and Cosmetic Act. *See* 21 U.S.C. § 355 *et seq.* ("the Hatch-Waxman amendments"); and 35 U.S.C. § 271(e)(2005). Congress intended the Hatch-Waxman amendments to be a mechanism to "get generic drugs into the hands of patients at reasonable prices – *fast*." *See In re Barr Labs.*, 930 F.2d 72, 76 (D.C. Cir. 1991). To this end, Congress established a statutory scheme that has been dubbed "thick" but one which is also carefully crafted to specifically set forth the burdens, entitlements and remedies of both the brand and generic pharmaceutical companies. *TorPharm, Inc. v. FDA*, No. 03-2401 (D.D.C. Jan. 2, 2004), hrg. tr. at 56 (J. Roberts)(attached as Ex. A to Bloodworth Decl.[1]); *see Glaxo v. Apotex*, 376 F.3d 1339, 1349 (Fed. Cir. 2004).

The Hatch-Waxman amendments establish a "highly artificial" act of infringement under 35 U.S.C. § 271(e) that enables brand pharmaceutical companies to enforce their patents at the same time a generic applicant is seeking approval from the Food and Drug Administration

[1] "Bloodworth Decl." refers to the attached Declaration of Shannon M. Bloodworth, Esq. in Support of Mylan Pharmaceuticals Inc.'s Motion to Strike Plaintiffs' Allegations Concerning Willful Infringement and to Bar All Discovery Related Thereto.

("FDA") for its Abbreviated New Drug Application ("ANDA"). *See Apotex, Inc. v. Thompson*, 347 F.3d 1335, 1338 (Fed. Cir. 2003) ("The Act also sought to facilitate the resolution of patent-related disputes over pharmaceutical drugs by creating a streamlined mechanism for identifying and resolving patent issues related to the proposed generic products."). Under the Hatch-Waxman amendments, this "highly artificial" act of infringement occurs at the time that a generic applicant submits its ANDA containing a paragraph IV certification to FDA, as opposed to the later time of market entry.[2] *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). The generic applicant is then required to notify the holder of the patents and the holder of the new drug application ("NDA") for the reference listed drug ("RLD"), a detailed statement that sets forth the complete legal and factual bases underlying its opinion that its product would not infringe any valid claim of the patents listed as covering the RLD.[3] *See* 21 U.S.C. § 355(j)(2)(B).

Under the Hatch-Waxman amendments, the holder of the patents or NDA have forty-five days from receiving the notification letter to evaluate the legal and factual bases set forth therein and to bring suit. If it chooses to bring suit within that time period, the FDA is statutorily prohibited from granting final approval to the ANDA until the earlier of thirty months or the resolution of the litigation. *See* 21 U.S.C. § 355(j)(5)(B)(iii). An award of attorneys' fees under 35 U.S.C. § 285 is allowed under the Hatch-Waxman amendments. The Hatch-Waxman

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[2] A paragraph IV certification is one of four certifications that may be submitted with an ANDA and is the one that an applicant submits if it is seeking FDA approval to market, use or sell the product prior to the expiration of the patents listed as covering the name brand drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* footnote 2, *infra*.

[3] The Hatch-Waxman amendments established the *Approved Drug Products With Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book"), published by FDA, where brand pharmaceutical companies can list the patents covering their RLDs. The patents listed in the Orange Book are commonly referred to as the "listed patents."

amendments therefore, "alter[] the normal application of patent law principles in various ways." *Apotex v. Thompson*, 347 F.3d at 1344 (citing, *e.g.*, 35 U.S.C. § 271(e)(2)).

Mylan's Abbreviated New Drug Application

Plaintiffs brought this suit after Mylan submitted an Abbreviated New Drug Application ("ANDA") seeking FDA approval to market and sell its pramipexole dihydrochloride tablet products, sold by Plaintiffs under the tradename MIRAPEX®. In their Complaint, Plaintiffs have alleged that Mylan's generic pramipexole products would infringe U.S. Patent No. 4,886,812 (the "'812 patent"), and specifically, that this filing constituted an act of "willful" infringement of the '812 patent.

In conformance with the requirements of the Hatch-Waxman amendments, Mylan's ANDA included a paragraph IV certification informing FDA that the manufacture, use or sale of Mylan's generic pramipexole dihydrochloride products would not infringe any valid claim of the '812 patent.[4] *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Mylan sent Plaintiffs a detailed notification letter setting forth and explaining Mylan's complete legal and factual bases underlying its opinion. *See* 21 U.S.C. § 355(j)(2)(B). Within forty-five days of receiving the notification letter, Plaintiffs brought this action against Mylan , thereby availing themselves of the Hatch-Waxman amendments protections – guaranteed thirty-months competition-free of Mirapex® sales – and its limitations – no monetary damages other than attorneys' fees.

[4] With its ANDA, Mylan also submitted a "Paragraph III certification" informing FDA that it would not market its generic pramipexole dihydrochloride products until the expiration of another patent owned by Plaintiffs, U.S. Patent No. 4,843,086 (the "'086 Patent"), which is expected to expire on November 23, 2007. However, in the related case, *Boehringer Ingelheim International GmbH v. Barr Pharmaceuticals Inc.*, 05-CV-0700 (D.Del.) (KAJ), Plaintiffs stated that the '086 patent is set to expire on June 27, 2006. *See* Amended Complaint (D.I. 7) at ¶ 25 (attached as Ex. B to Bloodworth Decl.).

SUMMARY OF ARGUMENT

In its Complaint, Plaintiffs allege that Mylan has infringed the '812 patent by submitting an ANDA, seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of its generic pramipexole dihydrochloride products. Complaint (D.I. 1) at ¶ 17. Plaintiffs also allege that this act of infringement is "premised upon a baseless assertion that the claims of the '812 patent are invalid" and that "Mylan disregarded its duty to exercise due care and committed an act of infringement premised on this baseless assertion of invalidity, rendering Mylan's infringement of the '812 patent willful." Complaint (D.I. 1) at ¶ 17. Plaintiffs' allegations of willfulness, evident from their own Complaint language, is based entirely on the "highly artificial" act of infringement of submitting an ANDA under 35 U.S.C. § 271(e)(2)(A). The Federal Circuit explicitly held in *Glaxo v. Apotex* that this is not grounds for a charge of willful infringement under the Hatch-Waxman amendments.

ARGUMENT

The Federal Circuit in *Glaxo v. Apotex*, 376 F.3d 1339 (Fed. Cir. 2004), held that under the unique statutory scheme set forth by the Hatch-Waxman amendments, even a baseless Paragraph IV certification does not constitute willfulness and, therefore, Plaintiffs' allegations must fail as a matter of law.

Mylan's Mere Filing of an ANDA Application and Certification Is Insufficient to Support a Claim of Willful Infringement

Rule 12(f) of the Federal Rules of Civil Procedure states that "a court may order stricken from any pleading any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). "The function of a 12(f) motion to strike is to avoid expenditure of time and money that necessarily arises from litigating spurious issues by disposing of those issues prior to trial." *Delaware Health Care v. MCD Holding Co.*, 893 F.

Supp. 1279, 1291 (D.Del. 1995)(quoting *Fantasy, Inc. v. Fogerty*, 984 F.2d 1524, 1527 (9th Cir.), *cert. denied*, 509 U.S. 903 (1993)). "Immaterial matter is that which has no essential or important relationship to the claim for relief or the defenses being pleaded." *Id.* at 1291-1292 (quoting 5A Charles A. Wright & Arthur R. Miller, Federal Practice and Procedure § 1382, at 706-07 (2d ed. 1990)). "Impertinent matter consists of statements that do not pertain, and are not necessary, to the issues in question." *Id.* at 1292 (quoting Wright, § 1382, at 711).

Mylan is entitled to have Plaintiffs' allegations of willfulness stricken as a matter of law because "the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)." *See Glaxo*, 376 F.3d at 1350-51. In *Glaxo*, the Federal Circuit reversed a district court's finding that the defendant had willfully infringed the plaintiff's patent by filing an ANDA. *Id.* at 1342, 1351. The court explained that the filing of an ANDA is a "highly artificial" act of infringement, giving rise to the limited set of consequences provided in 35 U.S.C § 271(e)(4). *Id.* at 1349. While attorney's fees may be awarded in an exceptional case (such as where a party engages in litigation misconduct or willful infringement), the type of conduct that may give rise to an award of attorney's fees for purposes of section 271(e)(4) has been limited by the Federal Circuit. *Id.* at 1350.

Specifically, the Federal Circuit in *Glaxo* held that "the mere filing of an ANDA cannot constitute an act of willful infringement compensable by attorney's fees under . . . the Hatch-Waxman Act." *Id.* at 1342; *see also id.* at 1349 ("the mere filing of an ANDA cannot constitute grounds for a willful infringement determination"). In addition, the court made clear that the submission of a paragraph IV certification – while potentially relevant to litigation misconduct – does *not* support a finding of willful infringement. *See id.* at 1350-51 ("the mere fact that a

company has filed an ANDA application *or certification* cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4).") (emphasis added); *see also id.* at 1350 (clarifying and reconciling *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339 (Fed. Cir. 2000)).

Several other courts have addressed this issue and dismissed allegations of willful infringement in Hatch-Waxman cases based on the Federal Circuit's *Glaxo* decision. *See, e.g.*, *Allergan, Inc. v. Alcon, Inc.*, No. 04-968 (GMS), slip op. (D. Del. July 26, 2005) (attached as Ex. C to the Bloodworth Decl.) ("The only act of infringement alleged in [the patentee's] complaint is [the defendant's] allegedly baseless paper NDA filing and Paragraph IV Certification with the FDA. Because a paper NDA filing cannot be considered willful, the [patentee's] complaint does not state any basis under which it could assert a claim of willful infringement."); *Aventis Pharma Deutschland GmbH v. Cobalt Pharms.*, 355 F. Supp. 2d 586, 590 (D. Mass. 2005) ("The only act of infringement alleged… is [the ANDA applicant's] filing of an ANDA and a paragraph IV certification with the FDA. Because this artificial act of infringement cannot be considered willful, Plaintiffs have averred no facts that can support a finding of willful patent infringement."); *Ortho-McNeil Pharm., Inc. v. Mylan Labs. Inc.*, No. 3:04-1689 (D.N.J. Apr. 18, 2005), hrg. tr. at 10:4 – 10 (J. Chesler) (attached as Ex. D to the Bloodworth Decl. ("The Court is satisfied that the *Glaxo* opinion of the Federal Circuit, indeed, as interpreted by the U.S. District Court for the District of Massachusetts in [*Aventis v. Cobalt*], in fact, correctly interprets *Glaxo* and the willful infringement claim is dismissed."). These cases all involved similar facts to those at issue here – Plaintiffs' allegation that a paragraph IV certification is "baseless" and therefore constitutes willful infringement. Therefore, Plaintiffs' allegations that Mylan has committed an act of willful infringement by filing a "baseless" paragraph IV certification should likewise be

dismissed. Complaint, Ex. A, at ¶ 17.

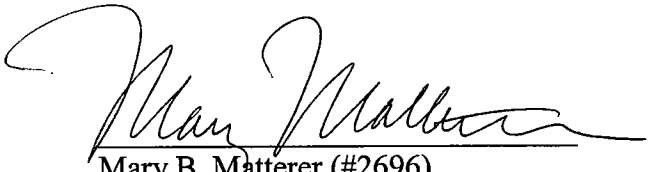
In summary, because Plaintiffs allege that Mylan has willfully infringed the '812 patent merely by submitting an ANDA application and certification, and because the Federal Circuit has found that such conduct is insufficient to support a finding of willful infringement, Plaintiffs' claim of willful infringement must be stricken as a matter of law. Because discovery is limited to issues raised in the pleadings, if the Court strikes Plaintiff's allegations of willfulness, it should bar any discovery related to those allegations as well.

CONCLUSION

For the reasons set forth herein, Mylan respectfully requests that this Court grant its Motion to Strike Plaintiffs' Allegations Concerning Willful Infringement, and issue an Order dismissing Plaintiffs' claim of willfulness and all discovery directed thereto.

Respectfully submitted,

MORRIS, JAMES, HITCHENS & WILLIAMS LLP



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CERTIFICATE OF SERVICE

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